OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

COMPLETING FINAL ACTION PACKAGES FOR STARS SUBMISSIONS

I. Purpose 1
II. Categories of final actions 2
III. Preparing a final action package 2
IV. Returning the submission(s) to the DCU to be finaled out 2
V. Completing the final action form 3
VI. Submitting the final action package 4
VII. Ensuring the accuracy of STARS 10
VIII. Creating an electronic file for the CVM records drive (R: Drive) 12
IX. Electronic submissions 13
X. Other considerations 14
XI. Complying with this guide 16
XII. References 16
Appendix 1 – Format for a scientific review 18
Appendix 2 – Format for a stand-alone submission summary 21

I. PURPOSE

This guide:

- Applies to all STARS submissions handled by ONADE personnel,
- Describes the information that should be submitted to the Document Control Unit (DCU) as part of a final action package,
- Provides a list of the steps to follow when the review of a submission is completed to assure the completeness of the administrative file,[1] and
- Establishes procedures for other activities related to the review of submissions and issuance of letters, such as the paper to be used for printing scientific reviews, letters, and other CVM work products, the use of submission summaries, and the formats for scientific reviews and submission summaries.

[1] See CVM Program Policy and Procedures Manual Guide 1243.2010 for ONADE's procedures for creating and keeping administrative records.

II. CATEGORIES OF FINAL ACTIONS

After the review of a submission is completed, the final action decisions can be separated into three categories:

1. Those that do not result in issuing a letter,
2. Those that result in letters signed by a Division Director or their designee, and
3. Those that result in letters signed by the Office Director or Center Director.

III. PREPARING A FINAL ACTION PACKAGE

Review division personnel[2] are responsible for preparing the final action package. They should ensure the completeness of the administrative file related to the matter of the submission by taking the following steps:

1. Returning the submission(s) that are being finaled out to the DCU (see section IV),
2. Completing the appropriate tracking/final action form (section V),
3. Submitting CVM work products that are part of the final action package (section VI),
4. Ensuring the accuracy of STARS (section VII), and
5. Creating an electronic file of CVM work products containing all parts of the final action package (section VIII).

IV. RETURNING THE SUBMISSION(S) TO THE DCU TO BE FINALED OUT

Review division personnel are responsible for returning **all** materials provided by the sponsor as the submission[3] and all other copies of the submission (including desk

[2] The "review division" is the division to which the submission is assigned for direct review and has primary (not consulting) responsibility for responding to the submission and preparing the final action package. "Review division personnel" are the individuals responsible for one or more aspects of preparing a final action package. These individuals are generally, but not exclusively, members of the review division. This term does not include those individuals responsible for preparing and returning consulting reviews.

copies,[4] copies made by ONADE personnel to support consulting reviews, and personal copies[5]) to the DCU. These materials may be returned either before the submission is finaled out or as part of the final action package. Rubber bands or boxes may be helpful to keep the materials together.

All transfers of administrative records must be performed by the DCU. If you have a continuing need to reference a submission on which a final action is being (or has been) completed, you should make a library loan transfer request to the DCU.[6] Similarly, if there is a need to provide a copy of the submission (usually the duplicate or triplicate) to other FDA personnel, e.g., field offices, you should submit a request to the DCU to transfer the copy. These requests should be made in the "Comments/Instructions to DCU" box of the final action form if they pertain to the submission being closed out. Transfer requests for any submission or volumes (jackets) of files may be made at other times by making a written request directly to the DCU.

V. COMPLETING THE FINAL ACTION FORM[7]

Review division personnel should complete the final action form appropriate to the submission(s) and ensure that:

1. The document code, document number, submission code, and submission number of each submission in the final action package are filled in on the form,

[3] In STARS, these materials are referred to as the AA package. The AA package includes the original, duplicate, triplicate, and any additional copies of the submission(s) provided by the sponsor, any supplied electronic media (CD's, diskettes, videos), and any other artifacts (e.g., drug containers, feed bags) submitted to CVM. Where actual drug products are among the artifacts, please contact the DCU for instructions regarding their placement in the administrative file or alternate disposition.

[4] A desk copy is an additional copy of all or part of the submission submitted by the sponsor directly to review personnel. All materials submitted to review personnel should be logged through STARS. Sponsors should be discouraged from submitting desk copies to review personnel.

[5] You may keep personal copies of key pages of submissions that pertain to critical issues. It remains your personal responsibility to control them and ensure that they are destroyed properly when they are no longer needed. This exception should not be used as a means to circumvent the procedures for returning copies of submissions to the DCU.

[6] A library loan transfer request also can be used to check out drug containers or other artifacts that may serve an educational purpose. However, the individual making the request has the responsibility to account for and ultimately return the artifacts to the administrative file.

[7] These forms are entitled "ONADE Final Action Form for STARS Submissions" and "ONADE Final Action Form for NADA and ANADA Approvals." See the STARS webpage on the CVM Intranet for copies of these forms (http://intranet.fda.gov/cvm/stars/stars3.htm).

2. The correct applicable final action code is checked,

3. Any special requests[8] are noted in the "Comments/Instructions to DCU" box, and

4. The routing of a final action package is completed according to CVM Program Policy and Procedure Manual Guide 1243.3060.

VI. SUBMITTING THE FINAL ACTION PACKAGE

A. Final actions that do not result in issuing a letter.

Where the submission is placed into the administrative file with no action (final action of "Submission filed with no review documentation; no letter sent"), review division personnel making the decision should write "FNR," the date of the decision, and their signature in the upper right quadrant of the first page of the original submission. The completed final action form should be stapled to the outside front face of the manila folder or volume containing the original submission.

Where the submission is filed without a reply to the sponsor but a review document (typically a memorandum to the file) is needed to document the decision (final action of "Submission filed with review documentation; no letter sent"), review division personnel making the decision should write "FNR with memo," the date of the review document, and their signature in the upper right quadrant of the first page of the original submission, and prepare the review document. The review document, printed on yellow paper,[9] should be included in the final action package. Do not document the rationale for the decision not to issue a letter on the submission itself or by completing the STARS "Summary Review" field[10] for the submission. The completed final action form should be stapled to the outside front face of the manila folder or volume containing the original submission. The review document should be attached to the left inside face of that folder or volume.

[8] Examples include requests to make changes in STARS data fields, requests for library loan transfers, or requests to transfer files to a district office.
[9] The use of yellow paper facilitates the easy identification of CVM-created records in the administrative file for later reference.
[10] The "Summary Review" field is found on the "Review Summary" screen accessible from the "Reviewer's Pending List" page in STARS.

B. Final actions that result in a letter signed by a Division Director or their designee.

Review division personnel are responsible for placing the letter issued to the sponsor and associated CVM work products in a manila folder that should accompany the submission(s) being finaled out. The use of a manila folder with the attached final action form identifies to the DCU work products that need to be placed in the administrative file or be issued to the sponsor.

1. The Final Action Form

   The completed final action form is stapled to the outside of the manila folder containing the letter being issued to the sponsor.

2. The Letter and Enclosures Issued to the Sponsor

   a. The letter issued to the sponsor (letter) is addressed to the company to the attention of whoever signed the cover letter of the submission unless there is alternative address information from the sponsor documented in the administrative file.

   b. The first page of the letter is printed on bond paper displaying the official pre-printed blue letterhead logo of the Department and the government watermark.[11] The remaining pages of the letter are printed on quality bond paper. Do not staple the letter.

   c. DCU, not the review division, is responsible for date stamping the letter.[12] The letter should not contain a cc: block or internal CVM routing or filing information footers.

   d. All enclosures itemized in the letter should be included behind the letter in the order mentioned. The enclosures should be individually stapled, if necessary.

   e. The letter and enclosures, covered with a transparent protector sheet, should be attached to the inside right face of the manila folder.

3. Envelope

[11] Do not use computer-created facsimiles of the letterhead logo for the letter.
[12] See CVM Program Policy and Procedure Manual Guide 1243.3340.

a. Review division personnel should provide the DCU with an envelope that:

   i. Is appropriately sized for the material to be sent to the sponsor,

   ii. Is pre-printed with the Department's return address,

   iii. Has an address on the envelope that matches the address of the letter, and

   iv. Has the DCU mail code (HFV-199), added by hand or printer, above the return address of the envelope to allow proper return of letter if the postal service is unable to deliver it.

b. The envelope should be attached to the inside right face of the manila folder behind the issuing letter and enclosures.

4. Copies of the Letter and Enclosures

   a. The official file copy of the letter and enclosures (the official file copy) should be printed on pink paper.[13] Do not staple any of these pages.

   b. The official file copy should include the cc:[14] and ec:[15] blocks and have the appropriate signatures needed for clearance.

   c. Where paper copies are still used, enough copies of the official file copy and enclosures, on white paper, should be included for distribution as indicated in the cc: block. The intended recipient's last name and mail code should be written in pencil in the upper right-hand corner on the first page of the copy to aid in their distribution. The DCU will distribute these copies as part of processing the final action package.

   d. The official file copy, and the other copies of the letter and enclosures for distribution, should be attached to the inside right face of the manila folder behind the issuing letter, enclosures, and envelope.

[13] Do not incorporate the letterhead logo into the official file copy. The use of pink paper facilitates later location of this letter in the administrative file.
[14] See CVM Program Policy and Procedure Manual Guide 1243.3060.
[15] See R: Drive SOPs.

5. Reviews and Other CVM-created Administrative Records

   a. Do not use memoranda to convey scientific reviews of STARS submissions.[16]

   b. The submission summary[17] (when prepared as a stand-alone document), primary and consulting reviews, and memoranda (e.g., memorandum of telephone conference, or note to file) should be attached (in that order) to the inside left face of the manila folder.

   c. Standardized formats for scientific reviews and submission summaries are described in Appendices 1 and 2, respectively.

   d. Reviews and all other CVM-created administrative records (excluding copies of the letter and enclosures) should be printed on yellow paper.[18]

C. Final actions that result in a letter signed by the Office Director or Center Director.

1. Letters of Import Ordinarily Signed by the Division Director

   The Office Director occasionally (and more rarely, the Center Director) signs letters that ordinarily would be signed by a Division Director when it is necessary to convey the importance or gravity of the letter's content. The Office Director also signs letters authorizing (or denying) the use of investigational animals or their products for food and letters granting (or denying) Expedited Review Status.

   The final action packages for these letters should be prepared following the same procedures as final actions resulting in letters signed by a Division Director (see section VI.B), except for the signature block and slight changes in routing to include the Office (or Center) Director.

[16] The practice of preparing a consulting review in the form of a memorandum originated when parts of what is now CVM (then Bureau of Veterinary Medicine) were located in different parts of the agency. At that time, standard operating procedures required that any information relayed between different parts of the agency be in the form of a memorandum. It is not appropriate for staffs that are now within the same Center to use a memorandum format to communicate information between them.
[17] See section X.A. for the description of a submission summary.
[18] The use of yellow paper facilitates the easy identification of CVM-created records in the administrative file for later reference.

2. Approval Letters

   The Center Director signs original application approvals and significant supplemental application approvals, e.g., new species, significant new claims, or changes in prescription/over-the-counter status. The ONADE Office Director signs most supplemental application approvals, except for routine manufacturing supplemental approvals that are issued by the Division of Manufacturing Technologies (HFV-140).[19]

   The following CVM work products should, if applicable to the submission, be included in Folder A or B:[20]

   a. The Final Action Form

      The appropriate final action form[21] is stapled to the outside of Folder A that contains the letter to be issued to the sponsor.

   b. The Letter and Enclosures Issued to the Sponsor

      i) The letter issued to the sponsor (letter) is addressed to the company to the attention of whoever signed the cover letter of the submission unless there is alternative address information from the sponsor documented in the administrative file.[22]

      ii) The first page of the letter is printed on bond paper displaying the official pre-printed blue letterhead logo of the Department and the government watermark.[23] The remaining pages of the letter are printed on quality bond paper. Do not staple the letter.

[19] See CVM Program Policy and Procedure Manual Guides 1243.3800 and 1243.5820 for information on preparing the approval letter and supporting review documents.
[20] See CVM Program Policy and Procedure Manual Guide 1243.3800 for the contents of Folders A and B.
[21] These forms are entitled "ONADE Final Action Form for STARS Submissions" and "ONADE Final Action Form for NADA and ANADA Approvals." See the STARS webpage on the CVM Intranet for copies of these forms (http://intranet.fda.gov/cvm/stars/stars3.htm).
[22] This is consistent with CVM Program Policy and Procedure Manual Guide 1243.5820. This guide (1243.5820) also has further information about the addresses to use in other approval documentation, e.g. the Federal Register Notice and Memorandum Recommending Approval.
[23] Do not use computer-created facsimiles of the letterhead logo for the letter.

iii) DCU, not the review division, is responsible for date stamping the letter.[24] The letter should not contain a cc: block or internal CVM routing or filing information footers.

iv) All enclosures itemized in the letter should be included behind the letter in the order mentioned. The enclosures should be stapled individually, if necessary.

v) The letter and enclosures, covered with a transparent protector sheet, should be placed in the inside right pocket of Folder A.

c. Envelope

i) Review division personnel should provide the DCU with an envelope that:

- Is appropriately sized for the material to be sent to the sponsor,
- Is pre-printed with the Department's return address,
- Has an address that matches the address of the letter, and
- Has the DCU mail code (HFV-199), added by hand or printer, above the return address of the envelope to allow proper return of the letter if the postal service is unable to deliver it.

ii) The envelope should be included in the inside right pocket of Folder A behind the letter and enclosures.

d. Copies of the Issuing Letter and Enclosures

i) The official file copy of the letter and enclosures (the official file copy) should be printed on pink paper.[25] Do not staple any of these pages together.

ii) The official file copy of the issuing letter should include the cc: and ec: blocks and have the appropriate signatures needed for clearance.[26]

[24]See CVM Program Policy and Procedure Manual Guide 1243.3340.
[25] Do not incorporate the letterhead logo into the official file copy. The use of pink paper facilitates later location of this letter in the administrative file.

iii) Where paper copies are still used, enough copies of the official file copy and enclosures, on white paper, are included for distribution as indicated in the cc: block. The intended recipient's name and mail code should be written in pencil in the upper right hand corner of the first page of the copy to aid in their distribution. The DCU will distribute these copies as part of processing the final action package.

iv) The official file copy, and the other copies of the letter and enclosures for distribution, should be included in the right pocket of Folder A behind the letter, enclosures, and envelope.

e. Reviews and Other CVM-created Administrative Records

i) The MRA, FOI Summary, and facsimile labeling should be included in the left pocket of Folder A, in that order. Additional copies should be placed in a separate folder if they are too bulky.

ii) The draft regulation and any environmental documents should be included in the right pocket of Folder A behind the letter, the official file copy, and other copies of the letter.

iii) The submission summary (when a stand-alone document), scientific reviews and memoranda (e.g., memorandum of telephone conference, or note to file) should be included in Folder B.

iv) The Memorandum Recommending Approval (MRA) should be printed on official blue letterhead memorandum paper using quality bond paper for the second and subsequent pages. The Freedom of Information (FOI) Summary, the draft regulation, copies of the facsimile or final printed labeling, and any environmental-related documents (Environmental Assessments, Finding of No Significant Impact, or Environmental Impact Statements) should be printed on white paper. All other CVM-created records (excluding copies of the letter and enclosures) should be printed on yellow paper.[27]

[26] See CVM Program Policy and Procedure Manual Guide 1243.3060 and R: Drive SOPs.
[27] The use of yellow paper facilitates the easy identification of CVM-created records in the administrative file for later reference.

VII. ENSURING THE ACCURACY OF STARS

Before the final action package leaves the review division, review division personnel are responsible for:

1. Confirming the accuracy of the information on the STARS DCU Routing Slip forwarded with the submission(s) and identifying any necessary changes in the "Comments/Instructions to DCU" box of the final action form.

2. Checking that all consulting reviews have been returned and routed through the DCU before routing the final action package for clearance and processing.

3. Completing the "Summary Review" field in STARS for all approvals except manufacturing supplemental approvals issued by the Division of Manufacturing Technologies (HFV-140). This field can be found in the "Review Summary" screen that is accessible from the "Reviewer's Pending List" in STARS.

   While not required, the review division is also strongly encouraged to complete the "Summary Review" field for all submissions because it can be an excellent review aid. Doing so would minimize the need to include cumulative chronologies of all submissions in the review of a submission. It also would permit anyone to use the STARS database (even many years later) to get a sense of the file's or application's history including decisions made and actions taken by CVM without having to go back to look at each submission.

   To the extent possible, the brief summary (up to 500 characters) should reflect the nature of the submission, any decisions made, and any other information of particular importance. While the contents of this field cannot replace a reading of CVM work products, it should be sufficient to answer basic administrative and historical questions. The primary reviewer[28] assigned the submission is in the best position to summarize and enter this information.

[28] The primary reviewer is the individual within the review division to whom the submission is assigned and is most responsible for overseeing the complete review of the submission.

VIII. CREATING AN ELECTRONIC FILE FOR THE CVM RECORDS DRIVE (R: DRIVE)

A. "Clean" electronic files

It is critical that electronic files of letters, reviews, and other documents be carefully examined to remove all traces of information that are not part of the body of the file before the file is considered complete. Examples of this trace information include comments and other editorial suggestions that result from the electronic review of the file. These comments and edits can be viewed in Microsoft Word by viewing the file after changing the "Display for Review" button in the Reviewing Toolbar to "Final Showing Markup." Any editorial changes and comments that have not been removed will become visible in one or more colors and are usually marked by a vertical black line in the left-hand margin. Accept or reject these visible editorial changes and delete the remaining comments.

B. Fonts used in electronic files

The principal font that should be used in letters and other documents that will be placed in public view is 12 point Times New Roman. For reviews and other "internal" documents, the acceptable principal fonts are 12 point Times New Roman and Arial. The 12 point Symbol font should be used to insert Greek, and similar, characters. The MathType plug-in for Microsoft Word should be used for statistical equations and similar uses. All fonts used in a document should be embedded in the document to prevent the possibility of font substitution when viewing the document. Font substitution could result in an unreadable document or, more likely, a misinterpretation of the document, e.g., an "m" is substituted for the Greek symbol mu (μ). To embed the document's fonts, click "Options" on the Tools menu of Microsoft Word, click the "Save" tab, select the "Embed TrueType fonts" check box, and finally "Save" the document.

C. Collecting electronic files of review documents

Review division personnel should collect the final versions of all electronic files for review documents associated with the final action (there should be an electronic file for each review document, e.g., review or memorandum). These electronic files should be attached to an email that is sent to the DCU at the time the final action package leaves the division for final clearance and processing. This email should be addressed to the "CVM DCU Final Action" mail account. The subject of this email

should be the document type code, the document number, the submission type code, and the submission number and the words "electronic files attached," e.g., "**I-012345-P-0123 electronic files attached**."

D. Creating the PDF file for the submission

The DCU will confirm that the final action package is complete and all electronic files are present. The DCU will scan and image the signed and date-stamped letter (including enclosures) and official file copy as Adobe Acrobat PDF files. They will combine these PDF files with the electronic files of review documents to create a single appropriately named and date stamped Adobe Acrobat file of all electronic files related to this final action. The DCU will then place this PDF file on the CVM Records Drive (R: Drive).

By tightly linking the final action of a submission to the creation of a complete electronic file for the final action, the R: Drive can be used as an official repository of CVM records as of the date that these procedures are implemented.

IX. ELECTRONIC SUBMISSIONS

Electronic submissions submitted in compliance with appropriate existing guidance do not have official paper copies of the submission. A description of the review procedures for electronically processing these submissions is available in the published guidance documents for each electronic submission type. To summarize briefly:

- When review of the submission results in a final action of "Submission filed with no review documentation; no letter sent," there is no paper work product to track because there is no final action package in the sense described in this guide. All review and final action processes occur electronically.

- When review of the submission results in the preparation of a review document or letter, the final action package for the submission will contain written document(s), e.g., memorandum, scientific review, or letter. The preparation and clearance of these written documents should follow the processes described in this guide. The "paper" and "electronic" portions of the final action package are combined and placed in the administrative file by the DCU before the submission is finaled out.

X. OTHER CONSIDERATIONS

A. Submission Summary

The submission summary is an "executive summary" of the submission and should **briefly** summarize the sponsor's requests, the administrative history of the submission(s), the relevant conclusions of any reviews performed, and the final decision(s) to be communicated to the sponsor in the letter.[29] The submission summary should not include a chronology or description of all previous submissions to the file or application.

Review division personnel should prepare a submission summary for each submission where a letter is issued except where specifically instructed otherwise by other CVM Program Policy and Procedure Manual Guides. Consistent placement of the submission summary in CVM's review documentation should aid reviewers (particularly those who may retrospectively review the file in the future) in easily identifying the substance of a submission, CVM's review, and any actions taken.

The form and location of the submission summary within CVM's review documentation for the submission depends on the complexity of the submission:

- The submission summary should be included at the beginning of the scientific review of the primary reviewer when a submission requires only one review to address the sponsor's requests and concerns, and the administrative oversight of the submission is not complicated.

- A stand-alone submission summary should be prepared when multiple scientific reviews are needed to address the sponsor's requests or concerns, or the administrative oversight is complicated.

A consulting scientific review should not contain a submission summary as described above. Rather, the consulting review should contain a summary of only that portion of the submission that relates to the consulting review. The purpose of

[29] The past practice of most staff was to summarize the submission under review in some manner, whether, for example, the summary was a "background" or "chronology" section of a review or a stand-alone document called a "document summary." Historically, the term document summary most properly referred to a summary of an application when the administrative history of the application was being summarized as part of the approval process. Some staff later adopted the document summary as a way to summarize submissions in INAD and JINAD files. Use of the term submission summaries avoids confusion, more accurately reflects current practices, and standardizes our review process.

a summary in a consulting review is to place the consulting review in proper context as it relates to the entire submission.

B. Consulting reviews

Some submissions are complex and require the scientific expertise of many individuals. Where the review of a submission results in consulting review requests, these requests should be issued within five days after the submission is date-stamped by the DCU. Issuing consulting review requests in this manner will ensure that the consulting review division has sufficient time to perform the review.

The consulting review division personnel are responsible for reviewing the information, preparing review document(s) consistent with this guide, and returning the submission and review document(s) through STARS to the requesting division in a timely manner.

The DCU will not forward consulting review packages to the requesting division if it finds obvious deficiencies, e.g., the review was prepared using a memorandum format or printed on other than yellow paper, or not all volumes of the submission that were forwarded to the consulting review division have been accounted for, in the consulting review package. Instead, the DCU will return the flawed consulting review package to the consulting division for correction. Similarly, if the requesting division finds the returned package is not consistent with this guide, they should return the consulting review package through STARS to the consulting division for correction.

C. Adding documents not associated with a submission to the administrative file

Occasionally, there is a need to place documentation, e.g., a memorandum, in the administrative file when there is no associated submission. To do this, attach the document to the right inside face of a manila folder and staple a blank final action form to the front face of the folder. Identify the document type and number, e.g., I-012345, on the form and write "**PLEASE PLACE IN FILE. NO ASSOCIATED SUBMISSION.**" in the "Comments/Instructions to DCU" box on the form. The DCU will place the document in the administrative file chronologically using the date the document reaches the DCU. Unfortunately, there is no present way for STARS to indicate that such a document, not associated with a submission, is present in the administrative file.

XI. COMPLYING WITH THIS GUIDE

The DCU will not final out any final action package that does not comply with this guide. Instead, the DCU will send an e-mail from the "CVM DCU Final Action" email account to the reviewer assigned the submission and the responsible Division Director (with copies to policy and DCU oversight staff in the ONADE's Office of the Director at the "CVM ONADE OD Final Action" email account) identifying the deficiencies of the final action package. At the same time, the DCU will return the final action package to the Division Director for correction. The DCU email will identify those deficiencies that were observed during their review. This list of deficiencies will not necessarily be complete. The review division should closely examine the returned final action packages for other unidentified deficiencies before returning the final action package.

The responsible review division should make the correction(s) as quickly as possible and return the final action package to the DCU to be finaled out. The responsible Division Director or assigned reviewer should notify all addressees of the original e-mail (by "Replying to All" in Microsoft Outlook) when the final action package has been corrected and is being returned to the DCU. Staff in the ONADE's Office of the Director are included in the notification so that the Office can evaluate whether the procedures related to the preparation of final action packages need to be revised, whether training is needed, or whether there are repeated serious systemic or localized failures in following the guide that need to be addressed by the Division Director.

XII. REFERENCES

CVM Program Policy and Procedure Manual Guides:

1243.2010, Responsibilities for Creating and Keeping Records

1243.3060, Final Document Routing and Copy Distribution for NADAs, ANADAs, INADs, JINADs, Master Files, and Suitability Petitions

1243.3340, Placing Stamp Dates on the Electronic Copies of Letters Issued by ONADE

1243.3800, Approval Process and Approval Package

1243.5820, Approval Letters

CVM Intranet webpage for STARS forms, http://intranet.fda.gov/cvm/stars/stars3.htm

R: Drive SOPs

APPENDIX 1 – FORMAT FOR A SCIENTIFIC REVIEW

I-012345-P-0123
Proprietary Name/Established Name[30]
Species and class description
Company name
Street address
Town, ST 01234
Month dd, YYYY

(JOB TITLE, e.g., MICROBIOLOGIST)'S REVIEW

I. Submission Summary

This section will **briefly** summarize the sponsor's requests, the administrative history of the submission(s), the relevant conclusions of any reviews performed, and the final decisions to be communicated to the sponsor in the letter. See section X.A of this guide for a full description of a submission summary and its contents.

II. Review

This section will document the review of the submission.

Formatting of this review:

Margins: The review should have the following margins: left margin is 1.25 inches; right, top, and bottom margins are 1 inch.

Fonts: The principal fonts that may be used are 12 point Times New Roman or Arial. See paragraph VIII.B of this guide for a full description of permissible fonts and their embedding in the review document.

Submission descriptor information: The submission descriptor information on the first page should be right justified with the submission identification on the first line being bolded. The date in the descriptor information should be the date the review was printed in final and will be considered the official date of the review for

[30] For new animal drugs that do not yet have a proprietary or established name, list the active ingredient, drug class or other identifier.

reference purposes. This date may differ from the signed date found in the signature block.

Review title: The title of the review should indicate the reviewer's job title, e.g., Microbiologist's Review, be centered, bolded, and in all caps.

Document header information: Reviews exceeding one page in length should have a right-justified two-line header beginning 0.5 inches from the top paper edge. The header consists of the principal submission, e.g., I-012345-P-0123, on the first line and the review title and a "Page x" entry on the second line (e.g., Microbiologist's Review, Page x). The header should be visible on the second and subsequent pages. Formatting the header is performed by clicking on "Page Setup" from the "File" menu of Microsoft Word, selecting the "Layout" tab, checking the "Different first page" box, and setting the "Header" to 0.5 inches from the edge.

Signature block: The signature block should be indented 3 inches from the left margin and leave room for the reviewer's signature and date above the signature block. The signature and date should be added contemporaneously. Their presence represents an acknowledgement that the signer assumes responsibility as the author of the document and that the document is complete and accurate to the best of their knowledge and ability.

III. Conclusions

This section should document the conclusions of the reviewer with respect to this submission. These conclusions form the basis for the recommendations described in section V.

IV. Transmit to Sponsor

This section should provide verbatim the reviewer comments that are to be included in the letter to the sponsor.

V. Recommendations

This section should document the recommendations of the reviewer with respect to this submission.

Reviewer signature and date review is completed
Reviewer Name, professional degree(s)
Job Title
Team Name, Mail Code

Follow current procedures for cc: and ec: blocks.

APPENDIX 2 – FORMAT FOR A STAND-ALONE SUBMISSION SUMMARY

I-012345-P-0123
Proprietary Name/Established Name[31]
Species and class description
Company name
Street address
Town, ST 01234
Month dd, YYYY

SUBMISSION SUMMARY

See section X.A of this guide for a full description of a Submission Summary and its contents.

Formatting of this document:

Margins: The submission summary should have the following margins: left margin is 1.25 inches; right, top, and bottom margins are 1 inch.

Fonts: The principal fonts that may be used are 12 point Times New Roman or Arial. See paragraph VIII.B of this guide for a full description of permissible fonts and their embedding in the review document.

Submission descriptor information: The submission descriptor information on the first page should be right justified with the submission identification on first line being bolded. The date in the descriptor information should be the date the review was printed in final and will be considered the official date of the submission summary for reference purposes. This date may differ from the signed date found in the signature block.

Title: The title "Submission Summary" should be centered, bolded, and in all caps.

Document header information: Summaries exceeding one page in length should have a right-justified two-line header beginning 0.5 inches from the top paper edge. The header consists of the principal submission, e.g., I-012345-P-0123, on the first

[31] For new animal drugs that do not yet have a proprietary or established name, list the active ingredient, drug class or other identifier.

line and the words "Submission Summary" and a "Page x" entry on the second line (e.g., Submission Summary, Page x). The header should be visible on the second and subsequent pages. Formatting the header is performed by clicking on "Page Setup" from the "File" menu in Microsoft Word, selecting the "Layout" tab, checking the "Different first page" box, and setting the "Header" to 0.5 inches from the edge.

Signature block: The signature block should be indented 3 inches from the left margin and leave room for the reviewer's signature and date above the signature block. The signature and date should be added contemporaneously. Their presence represents an acknowledgement that the signer assumes responsibility as the author of the document and that the document is complete and accurate to the best of their ability.

Reviewer signature and date summary is completed
Reviewer Name, professional degree(s)
Job Title
Team Name, Mail Code

Follow current procedures for cc: and ec: blocks.